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EXAMINER
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ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
10/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 6-24* is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 6-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a)☐ All   b)☐ Some *   c)☐ None of:

         1.☐ Certified copies of the priority documents have been received.

         2.☐ Certified copies of the priority documents have been received in Application No. _____.

         3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1.   Applicant is reminded of the proper language and format for an abstract of the disclosure. The submitted abstract has two paragraphs.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

2.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign

country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3.   Claims 1, 3, 6-9, 12-13, and 18, 20-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al (US Pat: 6,132,373).

Regarding claims 1, 6, Ito et al teaches an apparatus for measuring an intima-media thickness of a blood vessel [see abstract] that anticipates the claimed invention. Ito et al further teaches data analyzing device for receiving image data and calculating the intima media thickness of the blood vessel according to the image data [see abstract]; the digital data includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image [see abstract]; The data analyzing device includes a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image [see abstract]; a calculation device for detecting maximum value and a minimum value from among the luminance values corresponding to a predetermined number of the pixels; calculating the intima media thickness based on the maximum and minimum values [see abstract]. Ito et al teaches in the data analyzing device, a certain part of the image of the blood vessel including parts of the intima, media is extracted as a target part which is a line of pixels extending along the radius of the blood vessel [see column 2 lines 52-57]. The setting device calculates a moving average of the luminance values in the target part and sets a base position between the center of the blood vessel and the position in the vicinity of the inner intima wall of the blood vessel within the target part of the image [see column 2 lines 52-55]. A thickness calculation device that

includes one to five detection devices for detecting maximum and minimum values of luminance [see column 3 lines 39-54].

Ito also teaches adopting a composite thickness of the tunica intima and media i.e., an intima-media thickness (hereinafter referred to as an "IMT") of a carotid arteries as an index of judgment of arterial sclerosis has been studied in the world. Above all, a method of imaging a carotid artery using an ultrasound system, and measuring the IMT using an ultrasonic image for the purpose of diagnosis is attracting attention [see column 1 lines 20-25].

Ito teaches a data analyzing device for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. The digital image data includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image. The data analyzing device includes: a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image, on the basis of a moving average of the luminance values; and a calculation device for detecting a maximum value and a minimum value from among the luminance values respectively corresponding to a predetermined number of the pixels arranged from the base position toward a position of an outer adventitial wall on the image, and calculating the intima-media thickness on the basis of the maximum value and the minimum value [see abstract].

So the setting device that is within the data analyzing device is used to set the reference points of the tunica interna and externa (inherently) (emphasis added). Ito

reference makes any calculations based on reference points since the setting device

within the data analyzer, sets a base position (value, number, etc..) which is the

reference points or values (emphasis added).

Regarding claim 20, Ito et al teaches calculation device for calculating a

difference between a value representing the position of an inner intrimal wall and a

value representing the position of an inner advential wall, thereby obtaining the intima

media thickness [see column 4 lines 1-3]. Aventitia also known as lunica externa and it

is shown in fig 2. Measuring location of the border between the intima and media (the

outer intimal wall of the inner medial wall), and the location of the border between the

media and adventitia (outer media wall or the inner adventitial wall) [see column 9 lines

1-5]. Measuring location of the border is in fact measuring distance between

boundaries in the blood vessel (emphasis added).

Regarding claims 3, 7-9, 12-13, 18, Ito et al teaches the largest peak value is

observed at a point indicating a position on the adventitia (lunica externa) and a second

peak indicates a position on the intima [see fig 6C and column 9 lines 45-63]; two points

Xa and Xb are regarded as points indicating the locations of inner adventitial wall and

inner intimal wall [see column 9 lines 55-60]. An algorithm to calculate inner intima and

adventitia walls [see column 9 lines 64-67]; In fig 8-9, axis of abscissa indicates

positions of pixels arranged along the x axis from a start position of measurement, the

axis indicates luminance values observed in an image [see column 10 lines 1-5]. Image

data composed of m pixels ranging from the first pixel to the m-th pixel is extracted [see column 10 lines 12-15].

Plotting points of luminance values observed in the extracted image data, data composed of 50 pixels arranged along the X axis is extracted [see column 10 lines 20-23]; in order words a threshold value range of 50 pixels is extracted. An average value of luminance values is calculated in units of 20 pixels from the start position (first pixel and also consider as the reference point) [see fig 6B, column 10 lines 24-27]; A difference of the latest average value is calculated and determines whether the difference exceeds a predetermined value or fall below [see column 10 lines 28-33]; comparing peak value luminance to determine the locations of intima and externa. The luminance with largest peak value indicates the location of the externa [see column 10 lines 40-60]. The position or a position at which a decrease in the luminance value becomes equal to or smaller than DI [see FIG 9b] indicates the location of intimal wall [see column 11 lines 11-15].

Moving average value of luminance is calculated in units of 20 pixels from the start position of measurements; determine whether difference exceeds predetermined luminance value; the pixel having the largest luminance is in the region of adventia [see column 10 lines 45-60] and see figs 9A-6]. A change in tissular density occurring on the border between the tunica media adventitial is not large; distance resolution of 0.1 mm [see column 11 lines 25-35]. IMT values exceeding 1.1 mm may be colored in red and thus distinguished as a domain and an examiner collects IMT value with an evaluation table to be printed out; a line indicating an IMT of 1.1 mm may be drawn as a reference

and a domain of IMT values exceeding 1.1 mm may be colored [see column 15 lines 1-10].

Regarding claims 21-22 and 24, all the limitations are taught as set forth above by Ito et al. The above teaching anticipates the method as claimed. Ito et al teaches at least five detection devices and luminance detection device of Ito et al is used as brightness distribution acquisition; since luminance is another term used for brightness.

Ito teaches a data analyzing device for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. The digital image data includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image. The data analyzing device includes: a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image, on the basis of a moving average of the luminance values; and a calculation device for detecting a maximum value and a minimum value from among the luminance values respectively corresponding to a predetermined number of the pixels arranged from the base position toward a position of an outer adventitial wall on the image, and calculating the intima-media thickness on the basis of the maximum value and the minimum value [see abstract].

So the setting device that is within the data analyzing device is used to set the reference points of the tunica interna and externa (inherently) (emphasis added). Ito reference makes any calculations based on reference points since the setting device

within the data analyzer, sets a base position (value, number, etc..) which is the

reference points or values (emphasis added).

Claim Rejections - 35 USC § 103

4.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed
> or described as set forth in section 102 of this title, if the differences between the
> subject matter sought to be patented and the prior art are such that the subject
> matter as a whole would have been obvious at the time the invention was made
> to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was
> made.

5.   Claims 10-11, and 15-17, 19 and 23, are rejected under 35 U.S.C. 103(a) as

being unpatentable over Ito et al (US Pat: 6,132,373) in view of Ito et al (US Pat:

5,353,220).

Regarding claims 10-11, 15-17, and 23, all other limitations are taught as set

forth above. Ito et al further teaches an ultrasonic probe to emit waves to the common

carotid; Ultrasonic waves are reflected more greatly from the region of the intima [see

column 8 lines 10-16]. The region reflecting ultrasonic more greatly appears as a high-

luminance area in an ultrasonic image on the display screen of the ultrasonic apparatus

[see column 8 lines 13-15]; a change in luminance is measured in a direction in which a

blood vessel is traversed, whereby intima media thickness can be measured [see

column 8 lines 17-20]. Observing a far wall and near wall as a region of IMT to be

measured [see column 8 lines 55-60].

The above teaching is silent to a binarization process and obtaining tunica intima based on color distribution of Doppler signals; reconstructing images and three dimensional image data.

However, Ito et al teaches a color three dimensional image data using Doppler image data; a flow in a certain blood vessel is adopted as the object [see column 2 lines 55-60], data of blue color indicating flow in particular area and flow in red color in another area [see column 2 lines 62-67]; positions of blood vessels are extracted after binarization by threshold processing for each data in respective colors, and the extracted profile points are arranged so as to reconstruct three dimensional images [see column 3 lines 1-5]; displaying a 3D color Doppler image by respective color reconstructed [see column 3 lines 6-8]. Display data of red and data of blue showing a state of a flow of blood flow with binarization process [see column 3 lines 15-24].

Therefore, one with ordinary skill in the art would have been motivated to combine the Two Ito references by using the teachings of Ito et al to obtain the tunica intima; for the purpose of measuring IMT more accurately and easily than the conventional method.

Regarding claim 19, all other limitations are taught as set forth above.

The above teaching doesn't explicitly mention marking the extracted region on the display unit.

However, Ito et al teaches using different colors to mark a blood parameter in a display screen [see column 1 lines 35-50].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by marking the extracted region; in order to increase visualization.

6.   Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al (US Pat: 6,132,373) in view of Sano (US Pat: 5,615,680).

Regarding claim 14, all other limitations are taught as set forth above.

The above teaching doesn't explicitly teach a signal processing having a filter.

However, Sano et al teaches a phase detector includes a mixer, a low pass filter [see column 6 lines 25-30, lines 50-55]; A signal processor [see column 6 lines 13]; and signal processing section [see fig 1].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references; for the purpose of eliminating artifacts or noise in the image; thereby enhancing signal to noise ratio.

Response to Arguments

7.   Applicant's arguments filed 6/17/2009 have been fully considered but they are not persuasive. The abstract objection is maintained because the amended abstract still has two paragraphs. The abstract should be only one paragraph.

Applicant argues that the Ito reference doesn't teach setting means which set reference points of the tunica intima and tunica externa; and determine thickness based on reference points.

Examiner disagrees because Ito teaches a data analyzing device for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. The digital image data includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image. The data analyzing device includes: a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image, on the basis of a moving average of the luminance values; and a calculation device for detecting a maximum value and a minimum value from among the luminance values respectively corresponding to a predetermined number of the pixels arranged from the base position toward a position of an outer adventitial wall on the image, and calculating the intima-media thickness on the basis of the maximum value and the minimum value [see abstract].

So the setting device that is within the data analyzing device is used to set the reference points of the tunica interna and externa (inherently) (emphasis added). Ito reference makes any calculations based on reference points since the setting device within the data analyzer, sets a base position (value, number, etc..) which is the reference points or values (emphasis added).

Applicant also argues that Ito doesn't teach calculating any distances and thickness based on reference points.

Examiner disagrees because Ito reference makes any calculations based on reference points since the setting device within the data analyzer, sets a base position (value, number, etc..) which is the reference points or values (emphasis added).

Ito further teaches An IMT may be calculated by merely calculating a difference between the data items of the location of the inner intimal wall and inner adventitial wall, if it is allowed to measure the IMT roughly. However, for realizing the distance resolution of 0.1 mm, the IMT must be accurately calculated with the smallest error. Changes in the locations of the inner intimal wall and inner adventitial wall relative to the Z-axis direction are expressed with regression curves $fi(Z)$ and $fc(Z)$ in units of a predetermined range of pixels. An IMT is calculated based on a difference between points [$fi(Z0)$ to $fi(Zc)$ or $fe(Z0)$ to $fe(Zc)$] on the regression curves associated with each point (for example Z0 to Zc) on the Z axis indicating the range of pixels.

Conclusion

8.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to JOEL F. BRUTUS whose telephone number is

(571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00

PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768